

## AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A pharmaceutical composition comprising a KGF agonist and a gastrin compound that provides beneficial effects relative to each compound alone, and optionally a pharmaceutically acceptable carrier, excipient, or vehicle.

2-5. (Cancelled)

6. (Currently amended) A pharmaceutical composition as claimed in ~~any preceding~~ claim 1 wherein the ratio of KGF agonist to gastrin compound is selected to augment the activity of the KGF agonist or gastrin compound.

7. (Original) A pharmaceutical composition as claimed in claim 6 wherein the ratio of a KGF agonist to a gastrin compound is from about 1:1 to 1:110, 1:1 to 1:100, 1:1 to 1:75, 1:1 to 1:50, 1:1 to 1:25, 1:1 to 1:10, 1:1 to 1:5, and 1:1.

8-10. (Cancelled)

11. (Original) A pharmaceutical composition as claimed in claim 1 comprising an additive amount or synergistically effective amount of the KGF agonist and the gastrin compound in a pharmaceutically acceptable excipient, carrier, or vehicle.

12. (Original) A pharmaceutical composition as claimed in claim 1 comprising between 0.1 to 20, 0.1 to 30, 0.1 to 40, 0.1 to 50, and 0.1 to 60 micrograms/kg/day KGF agonist and 0.1 to 20, 0.1 to 30, 0.1 to 40, 0.1 to 50, and 0.1 to 60 micrograms/kg/day gastrin compound.

13. (Currently amended) A pharmaceutical composition as claimed in claim ~~2~~ 1 wherein the beneficial effects are one or more of the following: reduced or absent islet inflammation,

decreased disease progression, increased survival, or decreased symptoms of a disease or condition.

14-29. (Cancelled)

30. (Currently amended) A method of preparing a stable pharmaceutical composition of a KGF agonist comprising mixing a KGF agonist, a gastrin compound, and a pharmaceutically acceptable carrier, excipient, or vehicle effective to physically stabilize the KGF agonist and adapted to provide beneficial effects ~~preferably sustained beneficial effects~~.

31-34. (Cancelled)

35. (Currently amended) A method for inducing islet neogenesis in a subject comprising contacting islet precursor cells with a KGF agonist and a gastrin compound, ~~or a composition, or conjugate of any preceding claim~~ in a sufficient amount to increase proliferation of islet precursor cells in the subject thereby inducing islet neogenesis.

36. (Currently amended) A method for expanding and differentiating stem cells into insulin secreting cells comprising contacting the stem cells with an effective amount of a KGF agonist and a gastrin compound ~~or a composition or conjugate of any preceding claim~~.

37-41. (Cancelled)

42. (Original) A method for preventing and/or treating diabetes, the method comprising: contacting *ex vivo* a plurality of cells with a composition comprising a KGF receptor ligand and a gastrin/CCK receptor ligand in an amount sufficient to increase proliferation of islet precursor cells and the amount of insulin secreting islet cells; and administering the contacted plurality of cells to a mammal in need thereof, thereby preventing and/or treating the diabetes.

43. (Currently amended) A method of claim 42, wherein the amount of KGF receptor ligand in the composition is substantially lower than the minimum effective dose of KGF

receptor ligand required to reduce blood glucose in the diabetic mammal in the absence of a gastrin/CCK receptor ligand.

44. (Original) A method for preventing and/or treating diabetes, the method comprising administering to a mammal in need thereof a composition comprising a combination of a KGF receptor ligand and a gastrin /CCK receptor ligand, in an amount sufficient to increase the number of pancreatic insulin secreting  $\beta$  cells in the mammal; and determining the amount of islet neogenesis, thereby preventing and/or treating the diabetes.

45. (Currently amended) A method of claim 44, wherein ~~determining~~ the amount of islet neogenesis is ~~measuring~~ measured by a parameter selected from the group of: blood glucose, serum glucose, blood glycosylated hemoglobin, pancreatic  $\beta$  cell mass, serum insulin, pancreatic insulin content, and morphometrically determined  $\beta$  cell mass.

46-58. (Cancelled)

59. (Original) A method for inducing pancreatic islet neogenesis in a mammal, the method comprising administering a composition comprising a combination of a KGF receptor ligand and a gastrin /CCK receptor ligand, in an amount sufficient to increase the number of pancreatic insulin secreting  $\beta$  cells in the mammal.

60. (Original) A method for inducing islet neogenesis therapy in a cell of an animal, comprising contacting the cell with a nucleic acid sequence encoding a gastrin/CCK receptor ligand operably linked to an insulin promoter receptor ligand and a nucleic acid sequence encoding a KGF receptor ligand operably linked to a metallothionein promoter.

61-62. (Cancelled)

63. (Original) A nucleic acid construct comprising a nucleic acid sequence encoding a mammalian KGF receptor ligand operably linked to a heterologous promoter and a nucleic acid sequence encoding a mammalian gastrin/CCK receptor ligand operably linked to a heterologous

promoter.

64-67. (Cancelled)

68. (Original) A kit for preventing and/or treating diabetes, containing a composition comprising a gastrin/CCK receptor ligand and a KGF receptor ligand, a container, and instructions for use.

69. (New) A pharmaceutical composition of claim 1 wherein the KGF agonist comprises an amino acid sequence of SEQ ID NOs: 1, 2, 3, 4, 10, or 11.

70. (New) A pharmaceutical composition of claim 1 wherein the gastrin compound comprises the amino acid sequence of SEQ ID NOs. 5, 6, 7, 8, or 9.

71. (New) A method of claim 35 wherein the KGF agonist comprises an amino acid sequence of SEQ ID NOs: 1, 2, 3, 4, 10, or 11 and the gastrin compound comprises the amino acid sequence of SEQ ID NOs. 5, 6, 7, 8, or 9.